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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,111	12/12/2003	Jong Kil	A03P1079US01	3654

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
EVANISKO, GEORGE ROBERT	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,111	KIL ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6, 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hedberg et al (5740811). Hedberg shows in figures 1 and 2 the use of atrial unipolar signals and cross chamber sensing (IEGM diff) and in figure 13 the atrial unipolar signal and in figure 9 the cross chamber sensing (tip-can+SVC-can) and states that the synthesized ECG can use any combination of electrodes (columns 6 and 8). In addition, Hedberg distinguishes portions and identifies transitions related to the atrial signals from those corresponding to the ventricular signals and adjusts the relative amplitudes of the portions corresponding to atrial and ventricular signals as seen in column 5, lines 38-52 using non-linear amplification, column 8, line 53-column 10, line 51, the description of figure 13 of using different weightings/scaling factors for the signal amplitudes corresponding to different atrial and ventricular signals/locations and the use of a neural network being trained with a surface ECG to adjust the cross chamber IEGM (columns 5 and 6) and therefore inherently adjusts the amplitudes of the atrial and ventricular signals since the signal is processed to be similar to the training surface ECG. For claim 3, since Hedberg uses an atrial unipolar signal by itself, he will inherently identify near field and far field

signals in order to make a synthesized ECG similar to the training ECG. For claims 4, 5, 8, and 9, since the system/method is trained with a surface ECG, uses non-linear amplification, and weightings/scaling factors, the system/method possesses a predetermined ratio, such as 1:4 to 1:10 (in the alternative, see the 103 rejection below for claims 5 and 9), since this is the ratio of a normal ECG. Also, Hedberg will determine values representative of the peak magnitudes of the atrial and ventricular portions since Hedberg detects/determines these values for the non-linear amplification and neural network to produce the synthesized ECG. For claim 12, Hedberg discusses controlling the pacer or defibrillator with the synthesized ECG in columns 7 and 8, lines 1-10 and 10-14, respectively. For claims 13 and 14, Hedberg discusses the use of the IMD or an external device performing the adjustments/synthesizing in column 3, lines 1-13.

Claims 1-6 and 8-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll et al (6813514). Kroll describes in columns 16 and 17 the use of cross chamber sensing and atrial unipolar sensing. In addition, Kroll distinguishes portions and identifies transitions related to the atrial signals from those corresponding to the ventricular signals and adjusts the relative amplitudes of the portions corresponding to atrial and ventricular signals as seen in column 20, lines 30-32, column 20, line 47 to column 21, line 10, column 22, lines 20-30, and column 26, line 55-column 27, line 20. Since Kroll's cross chamber signal and atrial unipolar signals are a voltage signal and since Kroll uses weighting factors to affect the voltages (col 19, lines 45-62) he will adjust the relative amplitudes corresponding to atrial and ventricular signals. In addition, Kroll trains his system with a surface ECG to adjust the cross chamber IEGM and unipolar IEGM (columns 24-27) and therefore inherently adjusts the amplitudes of the atrial and ventricular signals since the signal is processed to be similar to the training surface ECG. For

claim 3, since Kroll uses an atrial unipolar signal by itself, he will inherently identify near field and far field signals in order to make a synthesized ECG similar to the training ECG. For claims 4, 5, 8, and 9, since the system is trained with a surface ECG, the system possesses a predetermined ratio, such as 1:4 to 1:10 (in the alternative, see the 103 rejection below for claims 5 and 9) since this is the ratio of a normal ECG. Also, Kroll will determine values representative of the peak magnitudes of the atrial and ventricular portions since Hedberg detects/determines these values for the non-linear amplification and neural network to produce the synthesized ECG. For claim 5, Kroll identifies the ventricular depolarization and repolarization using the baseline as transition points (see figure 8). For claim 12, Kroll discusses controlling the IMD with the synthesized ECG in column 18, lines 51-65. For claims 13 and 14, Kroll discusses the use of the IMD or an external device performing the adjustments/synthesizing in column 4, lines 44-50.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedberg et al or over Kroll et al.

Hedberg or Kroll discloses the claimed invention except for predetermined ratio being 1:4 to 1:10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ECG synthesizing system and method as taught by Hedberg or Kroll, with the predetermined ratio being 1:4 to 1:10 since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/735944. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application's claims are more narrow and meet the limitations of this application's claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 7/7/06 have been fully considered but they are not persuasive. The argument that Hedberg or Kroll use signals from two or more intracardiac electrodes and do not adjust relative portions of a "single cardiac signal" and that Kroll teaches away from "using a single cardiac signal to derive information pertaining to atrial and ventricular signals" is not persuasive since the claims do not claim that a single cardiac signal is used. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, original claim 15 had the system "using at least one electrode" (meaning one or more), the claims are "comprising" claims, open ended claims, and therefore do not preclude the use of atrial and ventricular electrodes, and it is unclear how making claim 15 broader by eliminating the use of the at least one electrode makes it a "single cardiac signal" or prevents Hedberg or Kroll from reading on the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
8/21/6

GRE
August 21, 2006